

expand inward between adjacent constraining members to contact the balloon, the remainder of the balloon prevented from expanding inward by the constraining members. As shown in Fig. 19, inflatable member 116 has been inflated and balloon contacting portions 124 have formed wings 104a-c in balloon 104.

[0076] The invention also contemplates embodiments in which inflatable member 116 is constructed with weaker and stronger portions such that upon inflation, only selected portions of the inflatable member, for example, the balloon contacting portions, expand inward, thereby obviating the need for constraining members. The inflatable member may also be provided with a thinner or weaker wall in the vicinity of the balloon contacting portions. Embodiments having an inflatable member with a rigid outer portion may be provided without a housing.

[0077] The inflatable member(s) may also constructed from multiple materials of varying rigidity or compliance. These materials may alternate radially around the perimeter of the inflatable member and/or longitudinally along its length. An example of such an inflatable member in a partially expanded state is shown at 116 in Fig. 20. Inflatable member 116 includes a plurality of balloon contacting portions 124. Balloon contacting portions 124 are made of a compliant material, for example nylon, silicon, latex, polyurethane. The remainder of the balloon may be made of non-compliant material, for example, polypropylene, polyimides, polyamides, and polyesters, such as PET and PEN (poly(ethylene naphthalenedicarboxylate)). Where an inflatable member such as that shown in Fig. 20 is used, the balloon contacting portions need not be separated by constraining members.

[0078] In other embodiments of the invention, such as those shown in Figs. 1-7, a plurality of inflatable members with balloon contacting portions are provided.

[0079] Because the extent to which the inflatable members may be inflated is easily controllable, the inventive devices can be particularly advantageous in configuring balloons where there are structures underlying the balloon such as marker bands, bonds or hubs. As shown in Fig. 21, inflatable member 116 applies a sufficient inward force to deform balloon 104 inward and produce wing 104a, and yet conforms to the shape of marker band 162 and hub 164 with minimal likelihood of damage. Also, by varying the extent of inflation of the inflatable members, the inventive devices may be used to configure balloons of different sizes disposed about catheters of varying sizes. To that

end, the inventive device may be outfitted with a control system which requires the input of one or more parameters such as the catheter size and/or the location and size of any underlying structure to provide for automatic configuring of balloons.

[0080] In the above embodiments, balloon contacting portions 124 apply substantially radially inward forces to medical balloon 104. It is also within the scope of the invention for the balloon contacting portions to apply a force having substantial radial and circumferential components. This may also be achieved, as shown in Fig. 22, by offsetting inflatable members 116 relative to the center of balloon 104. Inflatable members 116, as shown in Fig. 22, are partially inflated and apply a force having both radial and circumferential components to balloon 104. Inflatable members 116 are shown more fully inflated in Fig. 23.

[0081] The invention is also directed to any of the inventive devices disclosed herein in combination with a balloon catheter. Desirably, the balloon catheter is disposed in the channel of the inventive devices.

[0082] The invention is further directed to inventive methods of configuring a medical balloon. In accordance with one embodiment of the inventive methods, as shown in Fig. 12, medical balloon 104 may be disposed between one or more inflatable members 116, each of which has a balloon contacting portion 124. Any of the inflatable members disclosed herein or any other suitable inflatable members may be used.

[0083] As shown in Figs. 12, medical balloon 104 is at least partially inflated by supplying an inflation fluid thereto. An apparatus having a desired number of inflatable members is provided. The number of inflatable members will determine how many pleats are formed in the balloon. Inflatable members 116 are then inflated by delivering an inflation fluid such as a gas or a liquid to the inflatable members so that balloon contacting portions 124 deform portions of medical balloon 104 inward, as shown in Fig. 13. The inflatable members may be inflated simultaneously, sequentially or in any other suitable order. For example, going in a clockwise or counterclockwise direction about the balloon, inflatable members may be inflated in sequence. Another inflation sequence involves inflating every second inflatable member simultaneously or in sequence and then inflating the remaining inflatable members simultaneously or in sequence.

[0084] Optionally, inflatable members 116 may be supplied with a heated inflation fluid to

soften the inflatable members 116 so that they are better able to conform to any underlying structure and to, optionally, heat set the wings that are formed. Further, the heated fluid allows softening of medical balloon 104 to facilitate reconfiguration of the balloon.

[0085] Next, medical balloon 104 is at least partially deflated by withdrawing at least some of the inflation fluid from the balloon. Desirably, all of the inflation fluid is withdrawn from the balloon and inwardly deformed portions 156 of medical balloon 104 form a plurality of balloon folds. Where the inflatable members are longer than the body portion of the balloon, the folds will desirably extend to the cone sections of the balloon. Finally, inflatable members 116 are removed from about medical balloon 104. This may be accomplished by pulling balloon 104 through opening 148 in optional end cap 132 of optional end support 131.

[0086] Typically, as shown in Fig. 8, each of the inflatable members 116 has an inflation lumen 119 with an inflation port 117 which opens into the inflatable member at a first end of the inflatable member and the balloon has an inflation lumen 121 with an inflation port 123 which opens into balloon 104 at an end of the balloon opposite the first end of the inflatable member. Desirably, in accordance with the inventive methods, the inward force is applied progressively along the length of the medical balloon from one end of the balloon to the other end of the balloon. In accordance with the invention, the inflation ports of the inflatable members and the inflation ports of the balloon may be positioned in other locations relative to one another to allow for inflation to occur in other ways as well. For example, where the inflation ports are in the center of the balloon and in the center of the inflatable members, the inward force would be applied progressively outward in both directions from the center of the balloon.

[0087] Ideally, the balloon will be completely evacuated of fluid by means of the external pressure applied by the inflatable members exceeding that of the internal pressure supplied to the balloon. Once the balloon has been evacuated, a moderate vacuum may be drawn prior to the release of pressure from the inflatable members to preserve the shape of the newly configured balloon.

[0088] In accordance with the inventive methods, the inflatable members may be inflated simultaneously or in any other predetermined sequence. For example, where the plurality of inflatable members includes a first inflatable member located at a first end of the